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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,078	02/16/2000	Manuel Campos	PC10202A	5616
23913	7590	03/09/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			FOLEY, SHANON A	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/506,078

Applicant(s)

CAMPOS ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003 and 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20 and 22-35 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In the paper submitted December 1, 2003, applicant cancelled claims 1-17 and added new claims 18-35. Claims 18-35 are pending and under consideration.

Applicant submitted a status inquiry on February 4, 2004. In the inquiry, applicant states that a declaration was faxed to the examiner on July 24, 2003, but since then, no action had been received from the PTO.

In reply, a first action on the merits was mailed to applicant August 27, 2003, which addresses the declaration submitted by applicant on page 6. In the instant amendment to the claims submitted December 1, 2003, applicant states that the amendment is in response to the Office action dated August 27, 2003. Therefore, it appears that applicant has received the latest correspondence from the PTO. If this is not the case, applicant is requested to notify the examiner at the earliest convenience.

Applicant's arguments regarding the teachings of Van der Zee et al. are found persuasive. However, upon reconsideration, new grounds of rejection are required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20 and 22-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappel et al. (WO 90/02187), Zhu et al. (Vaccine. 1996; 14 (1): 61-69), Roeske et al. (sequence alignment of SEQ ID NO: 13 with Geneseq accession no: AAP50222, first entry: Jan 20, 1992 in

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EP13573-A), Russelljon et al. (sequence alignment of SEQ ID NO: 15 with Geneseq accession no: AAR11187, first entry: May 22, 1991 in WO 91/02799-A) and Babiuk et al. (sequence alignment of SEQ ID NO: 19 with Geneseq accession no: AAR37895, first entry: December 1, 1993 in WO 93/11792-A1).

The claims are drawn to a fusion protein comprising a first proteinaceous portion comprising the GnRH peptide, SEQ ID NO: 13 or SEQ ID NO: 15, and a second proteinaceous portion comprising BHV-1 gD, SEQ ID NO: 19. The claims also encompass a host cell comprising a vector expressing the fusion protein. The claims also encompass vaccines comprising the fusion protein, the vector expressing the fusion protein or a host cell expressing the fusion protein. A protective immune response is induced against BHV-1 and the sexual characteristics in a cow are inhibited as a result of administration of the vaccines.

Chappel et al. teach a recombinant fusion protein expressed from a gene in a host cell encoding a hepatitis B surface antigen (HBsAg) and luteinizing releasing hormone, otherwise known in the art as gonadotropin releasing hormone (GnRH), see page 6, the paragraph bridging pages 10 and 11 and claims 1, 4-6, 8 and 9. Administration of the fusion protein induced infertility in rabbits, see the second paragraph on page 12. Chappel et al. specifically suggest inducing infertility in cows with the fusion construct to increase the value of the cow, see the last paragraph on page 4 and the first paragraph on page 5. Chappel et al. do not teach BHV-1 gD.

Zhu et al. teach inducing mucosal and systemic immunity against BHV-1 with glycoprotein D, see the abstract, figures 2 and 3, "Induction of mucosal and systemic immunity...", "Protection from BHV-1 challenge" on page 65 and the discussion section.

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One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the HBsAg portion of the fusion protein of Chappel et al. with the strongly immunogenic BHV-1 gD of Zhu et al. to induce an immune response against GnRH and protect against BHV-1. One of ordinary skill in the art would have had a reasonable expectation of success of substituting HBsAg of Chappel et al. with BHV-1 gD of Zhu et al. because Chappel et al. specifically teach fusing the non-immunogenic luteinizing hormone to a highly immunogenic viral coat protein, see page 6 and the past paragraph on page 12, which is what gD from BHV-1 is, see the previous citations of Zhu et al. as well as the full paragraph of the second column on page 61. Therefore, one of ordinary skill in the art would view the incorporation of BHV-1 gD into the fusion protein of Chappel et al. as an obvious substitution to HBsAg.

The teachings of Chappel et al. overcome the deficiencies of Van der Zee et al., pointed out by applicant, because Chappel et al. specifically suggest fusing GnRH with other viral proteins. Further, while Van der Zee et al. teach insertion of GnRH within a P-fimbrial filament, Chappel et al. teach fusion of a viral protein and GnRH. Since the reference teaches how to make a fusion protein comprising a viral protein and GnRH and what properties the viral protein is required to have in order to induce an immune response against GnRH, the skilled artisan would have had a reasonable expectation of success for substituting one highly immunogenic viral coat protein for another from the teachings of Chappel et al.

Neither Chappel et al. nor Zhu et al. teach SEQ ID NOs: 13, 15 or 19. However, Roeske et al., Russelljon et al. and Babiuk et al. do, see the respective sequence alignments provided.

One of ordinary skill in the art at the time the invention was made would have been motivated to use conventionally known sequences in the art to elicit the appropriate immune

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response against a particular protein. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of substituting the sequences of Roeske et al., Russelljon et al. and Babiuk et al. into the combined vaccine of Chappel et al. and Zhu et al. because the GnRH protein and BHV-1 gD glycoprotein of Chappel et al. and Zhu et al., respectively, and the GnRH protein of Roeske et al. and Russelljon et al. and the BHV-1 gD of Babiuk et al. induce the same contraceptive properties and protective efficacy against BHV-1. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

***Allowable Subject Matter***

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or suggest SEQ ID NO: 29 or SEQ ID NO: 35.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley